No. 98-1109 (2)

In The Supreme Court of the United States

October Term, 1998

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
PETITIONERS,

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

On Petition For A Writ of Certiorari
To The United States Court of Appeals
For the Seventh Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii, eliminates jurisdiction under 28 U.S.C. §§ 1331 and 1346 over an action asserting constitutional and statutory challenges to Medicare regulations where the contentions alleged cannot be considered in the administrative review process and are unrelated to an individual claim?

PARTIES TO THE PROCEEDINGS

The Secretary's statement of "Parties to the Proceeding" is accurate as to the Petitioners. Respondent is the Illinois Council on Long Term Care, Inc.

The Illinois Council on Long Term Care, Inc., an Illinois not-for-profit corporation, in compliance with Supreme Court Rule 29.1, states that it has no affiliated corporations, either as a parent, subsidiary or otherwise.

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Respondent, the Illinois Council on Long Term Care, Inc., respectfully requests that this Court grant the petition for a writ of certiorari seeking review of the Seventh Circuits Opinion in this case. That opinion is reported at 143 F.3d 1072. However, the petition should be considered separately from *Your Home Nurse Services, Inc. v. Shalala,* No. 97-1489 (argued Dec. 2, 1998).

STATUTORY PROVISIONS INVOLVED

The provisions of 42 U.S.C. §§ 405(g), 405(h), 1395cc(h), and 1395ii are reproduced at Petitioner's Appendix to Petition at 24a-27a (hereinafter "Pet. App.").

The relevant provisions of 42 C.F.R. §§ 405.860, 488.408, and 498.3 are reproduced herein at Appendix, *infra*, A1-A8.

STATEMENT OF THE CASE

The Secretary's Statement of the Case omitted several important points. In 1987, Congress amended the Social Security Act with the Omnibus Budget Reconciliation Act, Pub. L. No. 100-203, 101 Stat. 1330 (1987). *See* Pet. App. at 14a. The amendments called for stricter guidelines and more severe penalties for providers not satisfying minimum health and safety standards. *Id.*; *See* 42 U.S.C. § 1395i-3. Implementing regulations for the 1987 amendments, however, did not take effect until July 1, 1995. Pet. App. at 1a. Before the new regulations went into effect, only 6% of nursing homes in Illinois were found to be out of compliance with the requirements to participate in Medicare and Medicaid. Pet. App. at 14a. After the new regulations went into effect in 1995, nearly 70% of nursing homes in Illinois were found deficient. Pet. App. at 2a, 14a. Respondent filed suit in district court asserting constitutional and statutory challenges to the new regulations.

Respondent contends that the drastic change in the rate of noncompliance is because the new regulations are vague and leave too much discretion to inspectors. Pet. App. at 2a. Respondent contends that the State Operations Manual used by inspectors has the effect of a regulation and therefore could be adopted only after notice-and-comment rulemaking under the Administrative Procedure Act, 5 U.S.C. § 553. Pet. App. at 2a. Respondent also contends that the administrative appeals process under the new regulations is so restrictive that it violates due process. Pet. App. at 2a. Administrative appeal rights are triggered only by imposition of a "remedy." *See* 42 C.F.R. § 498.3(b)(12). If a provider cures the alleged deficiency before a remedy is imposed, it loses those appeal rights. Thus, when an inspection results in deficiencies, a provider must choose between (a) refusing to correct the alleged deficiency and

risking termination of its provider agreement in order to appeal the deficiency; or (b) remedying the alleged deficiency and thereby forfeiting appeal rights. In addition, providers have no right to appeal the imposition of State monitoring or the loss of approval for a nurse's-aid training program. 42 C.F.R. § 498.3(b)(12) and (d)(10)(iii). Providers also have virtually no right to challenge the scope and severity of alleged deficiencies. 42 C.F.R.§498.3(d)(10)-(11) Providers may not appeal the choice of the remedy, including the factors considered in selecting the remedy. 42 C.F.R. § 488.408.

Significantly, providers also cannot assert the above mentioned claims nor challenge the new regulations themselves in the administrative review process. Administrative law judges are not empowered to hear such claims. *See* 42 C.F.R. § 405.860.[1/] Because administrative law judges cannot hear statutory or constitutional challenges, no "administrative record" is created regarding such claims for a federal court to review on appeal pursuant to 42 U.S.C. § 405(g). Pet. App. at 24a-25a. Furthermore, respondent, a trade association, is not entitled to any kind of administrative hearing on the constitutional and statutory claims asserted here.

Respondent's complaint asserted separate counts on behalf of its 75 members who participate solely in Medicaid,

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[1/] *E.g., Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 676, n. 6 (1986). (Medicare manual specifically prohibits administrative law judge from commenting on constitutionality of Medicare Act or regulations); *American Ambulance Serv. v. Sullivan*, 911 F.2d 901, 905 (CA3 1990) (it is not within the authority of the hearing officers to pass on the legality of the policies established by agency), *aff'd. without opinion*, 947 F.2d 934 (CA3 1991).

and separate counts for the remainder who participate in both Medicare and Medicaid. Pet. at 7, n. 5. The district court dismissed all counts of the complaint for lack of subject matter jurisdiction. Pet. App. at 3a. The Seventh Circuit reversed the district court's conclusion that the Medicaid counts should be dismissed for lack of jurisdiction. Pet. App. at 7a-9a. The Secretary does not challenge that part of the Seventh Circuit's decision. *See* Pet. at 7, n. 5. Accordingly, the Seventh Circuit's conclusion (Pet. App. at 9a) that a Medicaid provider is not forbidden from bringing a pre-enforcement challenge under § 1331 to a Medicaid regulation is not before the Court and, therefore, will not be addressed below.

REASONS FOR GRANTING WRIT

I. The Certiorari Petition Should be Granted but Should not be "Held Pending" Disposition of *Your Home* Because *Your Home* Is Distinguishable and its Disposition Will not Govern this Case.

We agree that the Court should grant the Secretary's certiorari petition to resolve a genuine split in the circuits. The Court should also grant the petition because respondent has filed a conditional cross-petition to review the Seventh Circuit's dismissal of respondent's challenge to the vagueness of the regulations. As explained in the cross-petition, thousands of nursing homes nationwide are being subjected to an unconstitutionally vague enforcement system, and the Seventh Circuit should not have dismissed the vagueness claim. The Court also should reject the Secretary's invitation to "hold" the petition pending disposition of *Your Home Visiting Nurse Services, Inc. v. Shalala*, No. 97-1489 (argued Dec. 2, 1998) (hereinafter "*Your Home*"). *Your*

Home is highly distinguishable and its resolution will provide no guidance here. It would be inappropriate to attempt to resolve summarily the circuit split in this case by relying on *Your Home*.

A. The Seventh Circuit's Decision Conflicts With a Sixth Circuit Decision in an Essentially Identical Case.

We agree with the Secretary's contention (Pet. at 14-15) that the Seventh Circuit's decision squarely conflicts with *Michigan Assn. of Homes & Services for the Aging, Inc. v. Shalala*, 127 F.3d 496 (CA6 1997), *reh'g, en banc, denied*, 1997 U.S. App. LEXIS 37154 (CA6 Dec. 17, 1997) ("*Michigan Association*"). The Seventh Circuit declared "we disapprove the sixth circuit's decision in *Michigan Association* across the board . . ." Pet. App. at 8a. *Michigan Association* largely is indistinguishable from the Medicare members' claims in this case. The plaintiff in *Michigan Association* raised many of the same challenges as respondent's Medicare members regarding the same statutes and regulations. This case thus presents a clear circuit conflict on a significant jurisdictional issue.

We also agree with the Secretary's contention that the Seventh Circuit's decision conflicts with other court of appeals decisions that have limited the holding in *Bowen v. Michigan Academy of Physicians*, 476 U.S. 667 (1986) ("*Michigan Academy*") in light of subsequent amendments to Part B of the Medicare program. Pet. at 15. There is disagreement among the lower courts regarding the effect of subsequent amendments on the holding in *Michigan Academy*. The district court below and the Sixth Circuit in *Michigan Association* concluded that the 1986 amendments eliminated the precedential value of *Michigan Academy*. Pet. App. at 5a, 18a; *see also* Pet. at 15 (citing cases).

But as the Seventh Circuit recognized, the 1986 amendments did not change the language of § 405(h) or § 1395ii. The operative language is the same as when *Michigan Academy* was decided. Pet. App. at 6a-7a. Other federal courts have reached the same conclusion: *Vermont Assembly of Home Health Agencies, Inc. v. Shalala*, 18 F. Supp. 2d 355, 362 (D. Vermont 1998) (even though the statutory scheme has been altered, this Circuit still recognizes that courts have subject matter jurisdiction over a challenge to a rule of general applicability); *Abbott Radiology Associates v. Sullivan*, 801 F. Supp. 1012, 1017-1018 (W.D.N.Y. 1992) ("the 1986 amendments did not displace the reasoning in *Michigan Academy* and courts have explicitly acknowledged *Michigan Academy's* continuing vitality"); *Abbey v. Sullivan*, 788 F. Supp. 165, 167 n.2 (S.D.N.Y. 1992), *aff'd*, 978 F.2d 37 (CA2 1992) ("contrary to defendant's assertions, the 1986 amendments to Medicare Part B do not render *Michigan Academy* a 'dead letter'"); *Griffeth v. Bowen*, 678 F. Supp. 942, 945 (D. Mass 1988) (there is no tension between *Michigan Academy* and the 1986 amendments). *See also United States, Qui Tam Body v. Blue Cross and Blue Shield of Alabama*, 156 F.3d 1098 (CA11 1998) (following *Michigan Academy* without suggesting that the 1986 amendments affected its holding). This case would be a good vehicle to resolve the confusion in the lower courts on this issue.

The issues raised here deserve careful consideration. Questions arise frequently regarding the scope of § 405(h)'s jurisdictional bar for statutory and constitutional challenges. Without clarification, the circuit split will spawn confusion in the lower courts and consume an increasing amount of judicial resources. Through this case the Court can shed light on a jurisdictional issue of widespread importance for both a federal agency and for providers nationwide that participate in Medicare. Moreover, the circuit split should be resolved promptly, because it encourages government officials to administer the same federal program in a nonuniform manner. Officials could apply excessively rigorous enforcement techniques within circuits that do not recognize federal question jurisdiction for constitutional and statutory claims. The circuit split also will encourage forum shopping by plaintiffs seeking to challenge Medicare regulations. Resolving this circuit split based on the outcome in a *distinguishable* case like *Your Home* would be inappropriate.

B. *Your Home* Is Highly Distinguishable.

The main issue in *Your Home* is whether a nursing facility was entitled to *more administrative review* than the Medicare statute actually requires. It dealt only peripherally with federal question jurisdiction under § 1331. In *Your Home*, the facility challenged a fiscal intermediary's discretionary decision not to reopen a "cost report" used to determine Medicare reimbursement. *Your Home Visiting Nurses Services v. Shalala*, 132 F.3d 1135, 1137 (CA6 1997), *cert. granted in part*, 118 S. Ct. 2318 (U.S. 1998). The facility appealed to a Provider Reimbursement Review Board, but the Board said it lacked jurisdiction. The Board said a fiscal intermediary's decision not to reopen a cost report was unreviewable pursuant to a regulation. The facility appealed to district court alleging jurisdiction under § 405(g), and also under § 1331, citing to *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). The facility argued that the Board and/or the district court should have jurisdiction to review the intermediary's refusal to reopen the cost report. *Your Home*, 132 F.3d at 1140.

Your Home is distinguishable both from this case and from Michigan Academy because, among other reasons, the facility in *Your Home* was not asserting facial statutory and

constitutional challenges to any regulations. The Secretary so argued in her merits brief in *Your Home*:

> [Petitioner's claim] does not attack the underlying validity of a regulation; it simply avers that the intermediary misapplied a regulation when determining the amount of reimbursable owners' compensation costs owed to petition. Thus, petitioner's contentions do not resemble the sort of facial challenge that the Court in *Michigan Academy* found to be beyond the scope of Section 405(h)'s preclusive effect.

Your Home, Respondent's Br. at 31, 1998 WL 644663. *Your Home* arguably involves the sort of "amount determinations" and "quite minor matters" that *Michigan Academy* said Congress meant to foreclose by section 405(h). *See Michigan Academy*, 476 U.S. 667, 680. By contrast, respondent's claims in this case are facial challenges to the underlying validity of the regulations and are "beyond the scope of Section 405(h)'s preclusive effect."

Your Home also is distinguishable because the facility had the right to appeal the amount of reimbursement within the administrative process, but failed to do so. *See Your Home*, Respondent's Br. at 12. The facility in *Your Home* also had access to 42 U.S.C. § 1395w(f)(1), a review mechanism that would allow it to challenge questions of law or regulations in federal court after a review board certified that it lacked authority to decide the question. *See Your Home*, Respondent's Br. at 11, n. 3 and 31. ("Section 1395oo explicitly affords Part A providers, such as petitioner, an avenue to challenge both the amount of Medicare payments and the methods by which those payments are calculated."). Here, neither respondent nor any of its members could raise their constitutional and statutory challenges in any administrative setting. Section 405(h) may well preclude federal question jurisdiction over the fiscal intermediary's refusal to reopen a cost report in *Your Home*. But § 405(h) does *not* preclude jurisdiction over the constitutional and statutory claims alleged here. The disposition of *Your Home* will not govern this case. The certiorari petition should be granted, but this case should be considered separately from *Your Home*.

II. The Seventh Circuit's Jurisdictional Ruling Should Be Affirmed. The Court Followed Controlling Precedent In Concluding That Jurisdiction Exists Under Section 1331.

The Secretary argues the Seventh Circuit's decision conflicts with *Heckler v. Ringer*, 466 U.S. 602 (1984) ("*Ringer*") and that the court misconstrued *Michigan Academy* Pet. at 12-13. In fact, the court correctly followed this Court's more recent decisions in *Michigan Academy* and *McNary v. Haitian Refugee Center*, 498 U.S. 479 (1991), instead of *Ringer*, for several reasons.

First, *Ringer* is distinguishable from this case for the same reasons this Court cited when it distinguished *Ringer* in *McNary*, 498 U.S. at 494-496. *Ringer* involved claims for reimbursement for a surgical procedure that the Court concluded were not "collateral" to claims for benefits. Similar to the claimants in *Your Home*, the claimants in *Ringer* could have pursued administrative remedies for processing reimbursement claims, *id.* at 494, and had an adequate remedy in § 405(g) for challenging in court all aspects of the Secretary's denial of their claims for payment. *Id.* at 495. By contrast, the claims here *are* collateral to individualized or substantive claims for benefits and "respondents would not as a practical matter be able to obtain meaningful judicial review" of their claims after exhausting

administrative remedies. *McNary* 498 U.S. at 495-496.

Second, the court of appeals was right in following *Michigan Academy* and *McNary* instead of *Ringer*, because they are more recent and set forth an analysis that is more precise and truer to congressional intent than the analysis in *Ringer*. In *Michigan Academy*, this Court set forth an analysis for jurisdictional issues like those at issue here. "We begin with the strong presumption that Congress intends judicial review of administrative action." 476 U.S. at 670-71. "[O]nly upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review." *Id.* at 671. With those principles in mind, this Court analyzed the statutory provisions the Secretary claimed eliminated federal question jurisdiction. *Id.* at 673. Those same provisions are at issue here. The Court also considered the legislative history and concluded that federal question jurisdiction exists for matters that are not determined in an administrative hearing:

> [c]areful analysis of the governing statutory provisions and their legislative history thus reveals that Congress intended to bar judicial review only of determinations of the amount of benefits to be awarded under Part B. Congress delegated this task to carriers who would finally determine such matters in conformity with the regulations and instructions of the Secretary. We conclude, therefore, that those matters which Congress did not leave to be determined in a "fair hearing" conducted by the carrier– including challenges to the validity of the Secretary's instructions and regulations–are not impliedly insulated from judicial review. . . .

Michigan Academy, 476 U.S. at 678. The foregoing language and similar statements in *Michigan Academy* constitute the critical holding the Seventh Circuit followed here. *See* Pet. App. at 4a. The Seventh Circuit simply followed, in straightforward fashion, this Court's interpretation of particular statutes and their legislative history.

This Court employed the same analysis and followed *Michigan Academy* five years later in *McNary v. Haitian Refugee Center*, 498 U.S. 479 (1991). In *McNary*, this Court upheld federal question jurisdiction over systemic and constitutional challenges to regulatory procedures adopted under the Immigration Reform Act ("IRA"). As in *Michigan Academy*, this Court analyzed the language of the statute and the administrative review scheme. This Court recognized that the administrative review provisions of the IRA were tailored to individual determinations of "an application" and a denial thereof. *McNary* at 492. The review provisions did not refer "to general collateral challenges to unconstitutional practices and policies used by the agency in processing applications." *Id.*

McNary further discussed and followed *Michigan Academy:* "[In *Michigan Academy*] [w]e recognized that review of individual determinations of the amount due on particular claims was foreclosed, but upheld the collateral attack on the regulation itself, emphasizing the critical difference between an individual 'amount determination' and a challenge to the procedures for making such determinations." *McNary*, 498 U.S. at 498. "Decision in this case is therefore supported by our unanimous holding[2/] in *Bowen* [*v. Michigan Academy*]." *Id.* at 497.

This Court's more recent decisions continue to follow or cite to *Michigan Academy* and *McNary*, confirming their analytical approach. *Reno v. Catholic Soc. Servs.*, 509 U.S. 43, 63-64 (1993) ("As we stated recently in *McNary*, there

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[2/] Chief Justice Rehnquist did not participate in the case.

is a 'well-settled presumption favoring interpretations of statutes that allow judicial review of administrative action'" also citing *Michigan Academy*); *Thunder Basin Coal Company v. Reich*, 510 U.S. 200, 213 (1994) (citing *Michigan Academy* and discussing but distinguishing *McNary*); *Gutierrez De Martinez v. Lamagno*, 515 U.S. 417, 424 (1995) ("federal judges traditionally proceed from the 'strong presumption that Congress intends judicial review.'", citing *Michigan Academy*). The Seventh Circuit correctly applied the analysis from this Court's more recent cases, and concluded that jurisdiction exists for respondent's claims.

The Secretary says *Michigan Academy* does not support jurisdiction here because § 405(g) expressly confirms the district court's power to "review . . . the validity of [the Secretary's] regulations" when it reviews the Secretary's final decision. Pet. at 13-14. This Court rejected the same argument in *McNary*. In *McNary*, the Immigration and Naturalization Act provided for administrative review and thereafter judicial review by the court of appeals regarding decisions on amnesty applications. This Court concluded that the limited post-exhaustion judicial review provided by the INA could not adequately address the statutory and constitutional claims at issue. *McNary*, 498 U.S. at 484, 496-97. This Court recognized that administrative and judicial review of an agency decision "is almost always confined to the record made in the proceeding at the initial decision making level." *Id.* at 496. This Court noted that the lack of an adequate administrative record at the initial decision-making level meant that the court of appeals would have no "meaningful basis upon which to review application determinations." *Id.* at 497.

The same analysis applies here. Respondent's statutory and constitutional claims cannot be considered in the administrative review process. Administrative law judges

have no authority to hear statutory or constitutional challenges to regulations.[y] Accordingly, there would be no evidence taken and no administrative record compiled regarding respondent's statutory and constitutional claims for a federal court to review in an appeal pursuant to § 405(g). As in *McNary*, restricting judicial review to the limited scope of § 405(g) "is the practical equivalent of total denial of judicial review of generic constitutional and statutory claims." *McNary* at 497. As the Court reiterated in *Thunder Basin Coal Company v. Reich*, 510 U.S. 200, 207 (1994), whether "a statute is intended to preclude initial judicial review is determined from the statute's language, structure, and purpose, its legislative history, and *whether the claims can be afforded meaningful review.*" (emphasis added) (citations omitted). Respondent's claims here cannot be meaningfully addressed or reviewed in the administrative process. Under *McNary* and *Michigan Academy*, jurisdiction exists under § 1331.

B. The Sixth Circuit's Conflicting Decision Failed to Follow Controlling Precedent and Should be Overruled.

The Sixth Circuit's decision in *Michigan Association*, 127 F.3d 496 (CA6 1997), failed to follow the analysis set forth in *McNary* and other recent Supreme Court cases. The Sixth Circuit tried to distinguish *McNary*, stating that the *McNary* claimants had no meaningful judicial review, but that the claimant in *Michigan Association* did have

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[y] *E.g., Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 676, n. 6 (1986); *American Ambulance Serv. v. Sullivan*, 911 F.2d 901, 905 (CA3 1990), *aff'd without opinion*, 947 F.2d 934 (CA3 1991).

meaningful judicial review. 127 F.3d at 501. The Sixth Circuit failed to recognize, however, that statutory and constitutional challenges *cannot* be raised in administrative proceedings, and therefore, an adequate administrative record for a federal court to review on appeal will never be created.

The Sixth Circuit also tried to distinguish *McNary*, stating that the statutory language at issue in *McNary* regarding "a determination respecting an application for adjustment of status" is much more restrictive than the language of § 405(h). 127 F.3d at 501. However, the provision at issue in *McNary* is very similar to 42 U.S.C. § 1395cc(h)(1), which incorporates § 405(g) into the Medicare Act, regarding "a determination of the Secretary that it is not a provider of services." That language is just as indicative of individualized determinations as the language in *McNary*. The Sixth Circuit's attempt to distinguish *McNary* is therefore meritless.

C. The Seventh Circuit's Decision Is Consistent with Recent Supreme Court and Circuit Court Cases.

The Secretary contends that the Seventh Circuit's decision conflicts with the great weight appellate authority. Pet. at 14. As demonstrated above, the court's decision is consistent with the great weight of recent Supreme Court authority, particularly *Michigan Academy*, *McNary*, and *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43 (1993). *Compare Thunder Basin Coal Company v. Reich*, 510 U.S. 200 (1994) (distinguishing *McNary*).

The Seventh Circuit's decision also is consistent with a recent well reasoned decision from the Eleventh Circuit, *United States, Qui Tam Body v. Blue Cross and Blue Shield*

of Alabama, Inc., 156 F.3d 1098 (CA11 1998). There, the Eleventh Circuit analyzed *Weinberger v. Salfi*, 422 U.S. 749 (1975); *United States v. Erika, Inc.*, 456 U.S. 201 (1982); *Heckler v. Ringer;* and *Bowen v. Michigan Academy*, declaring:

> Perhaps most clearly of the four Supreme Court cases analyzing the jurisdictional limitations contained in the Medicare Act, *Bowen* demonstrates that subsection 405(h), viewed within the context in which it was drafted and made applicable to Medicare, simply seeks to preserve the integrity of the administrative process Congress designed to deal with challenges to amounts determinations by dissatisfied beneficiaries, not to serve as a complete preclusion of all claims related to benefits determinations in general.

Body, 156 F.3d at 1109. The Eleventh Circuit concluded that actions "which do not seek payment from the government and could not be brought under Section 405, are therefore, not barred by subsection 405(h)." *Id.* at 1104. The Eleventh Circuit's decision is consistent with the Seventh Circuit's decision here, and accordingly, also conflicts with the Sixth Circuit's decision in *Michigan Association*.

The Secretary contends (Pet. at 15) that the court of appeals' decision is inconsistent with *St. Francis Medical Center v. Shalala*, 32 F.3d 805, 812-813 (CA3 1994), *cert. denied*, 514 U.S. 1016 (1995). *St. Francis* is distinguishable for the same reasons *Your Home* is distinguishable. In *St. Francis*, the court held that avenues of administrative review were available for claims regarding annual cost reports. 32 F.3d at 812 (discussing 42 U.S.C. § 1395oo(f)(1)). No such administrative review is available for the statutory and constitutional claims here.

CONCLUSION

For the foregoing reasons, the certiorari petition should be granted, but this case should be considered separately from *Your Home Visiting Nurse Services, Inc. v. Shalala*, No. 97-1489.

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APPENDIX A

(1) Section 405.860 of Title 42, Code of Federal Regulations, provides:

Review of national coverage decisions (NCDs).

(a) **General.**

(1) HCFA makes NCDs either granting, limiting, or excluding Medicare coverage for a specific medical service, procedure or device. NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act. An NCD is binding on all Medicare carriers, fiscal intermediaries, PROs, HMOs, CMPs, and HCPPs when published in HCFA program manuals or the Federal Register.

(2) Under section 1869(b)(3) of the Act, only NCDs made under section 1862(a)(1) of the Act are subject to the conditions of paragraphs (b) through (d) of this section.

(b) **Review by ALJ.**

(1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

(c) **Review by Court.**

(1) A court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. The court may not invalidate an

NCD except upon review of the supplemented record.

(2) A Federal court may not hold unlawful or set aside an NCD because it was not issued in accordance with the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) or section 1871(b) of the Act.

(d) **Remands--**

(1) Secretary's action. When a court remands an NCD matter to the Secretary because the record in support of the NCD is incomplete or otherwise lacks adequate information, the Secretary remands the case to HCFA in order to supplement the record.

(2) Remand to HCFA. HCFA supplements the record with new or updated evidence, including additional information from other sources, and may issue a revised NCD.

(3) Final Actions.

(i) The proceedings to supplement the record, are expedited.

2. Section 488.408 of Title 42, Code of Federal Regulations, provides:

Selection of remedies.

(a) **Categories of remedies.** In this section, the remedies specified in Sec. 488.406(a) are grouped into categories and applied to deficiencies according to how serious the noncompliance is.

(b) **Application of remedies.** After considering the factors specified in Sec. 488.404, as applicable, if HCFA and the State choose to impose remedies, as provided in paragraphs (c)(1), (d)(1) and (e)(1) of this section, for facil-

ity noncompliance, instead of, or in addition to, termination of the provider agreement, HCFA does and the State must follow the criteria set forth in paragraphs (c)(2), (d)(2), and (e)(2) of this section, as applicable.

(c) **Category 1.**

(1) Category 1 remedies include the following:

(i) Directed plan of correction.

(ii) State monitoring.

(iii) Directed in-service training.

(2) HCFA does or the State must apply one or more of the remedies in Category 1 when there--

(i) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

(3) Except when the facility is in substantial compliance, HCFA or the State may apply one or more of the remedies in Category 1 to any deficiency.

(d) **Category 2.**

(1) Category 2 remedies include the following:

(i) Denial of payment for new admissions.

(ii) Denial of payment for all individuals imposed only by HCFA.

(iii) Civil money penalties of $50-3,000 per day.

(2) HCFA applies one or more of the remedies in Category 2, or, except for denial of payment for all individuals, the State must apply one or more of the remedies in Category 2 when there are--

(i) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

(3) HCFA or the State may apply one or more of the remedies in Category 2 to any deficiency except when--

(i) The facility is in substantial compliance; or

(ii) HCFA or the State imposes a civil money penalty for a deficiency that constitutes immediate jeopardy, the penalty must be in the upper range of penalty amounts, as specified in Sec. 488.438(a).

(e) **Category 3.**

(1) Category 3 remedies include the following:

(i) Temporary management.

(ii) Immediate termination.

(iii) Civil money penalties of $3,050-$10,000 per day.

(2) When there are one or more deficiencies that constitute immediate jeopardy to resident health or safety--

(i) HCFA does and the State must do one or both of the following:

(A) Impose temporary management; or

(B) Terminate the provider agreement;

(ii) HCFA and the State may impose a civil money penalty of $3,050-$10,000 per day, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section.

(3) When there are widespread deficiencies that constitute actual harm that is not immediate jeopardy, HCFA and the State may impose temporary management, in addition to Category 2 remedies.

(f) **Plan of correction.**

(1) Except as specified in paragraph (f)(2) of this section, each facility that has a deficiency with regard to a requirement for long term care facilities must submit a plan of correction for approval by HCFA or the State, regardless of—

(i) Which remedies are imposed; or

(ii) The seriousness of the deficiencies.

(2) When there are only isolated deficiencies that HCFA or the State determines constitute no actual harm with a potential for minimal harm, the facility need not submit a plan of correction.

(g) **Appeal of a certification of noncompliance.**

(1) A facility may appeal a certification of noncompliance leading to an enforcement remedy.

(2) A facility may not appeal the choice of remedy, including the factors considered by HCFA or the State in selecting the remedy, specified in Sec. 488.404.

3. Section 498.3 of Title 42, Code of Federal Regulations, provides in pertinent part:

Scope and applicability.

(b) **Initial determinations by HCFA.** HCFA makes initial determinations with respect to the following matters:

(12) With respect to an SNF or NF, a finding of noncompliance that results in the imposition of a remedy specified in Sec. 488.406 of this chapter, except the State monitoring remedy, and the loss of the approval for a nurse-aide training program.

(d) **Administrative actions that are not initial determinations.** Administrative actions that are not initial determination (and therefore not subject to appeal under this part) include but are not limited to the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions or requirements for participation or for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement

have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution--

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to an SNF or NF-

(i) The finding that the SNF's or NF's deficiencies pose immediate jeopardy to the health or safety of its residents;

(ii) Except as provided in paragraph (b)(13) of this section, a determination by HCFA as to the facility's level of noncompliance; and

(iii) The imposition of State monitoring or the loss of the approval for a nurse-aide training program.

(11) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(12) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(13) The determination that requirements imposed on a State's laboratories under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements.

(14) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(15) A decision by the State survey agency as to when to conduct an initial survey of a prospective provider or supplier.